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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,008

11/17/2003

Masaaki Ikeda

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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

02/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/713,008</p>	<p>Applicant(s) IKEDA ET AL.</p>	
	<p>Examiner FEREYDOUN G. SAJJADI</p>	<p>Art Unit 1633</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 09 January 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1,2,6,16-33,37 and 38.
Claim(s) withdrawn from consideration: 7-11.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Fereydoun G Sajjadi/
Examiner, Art Unit 1633

Continuation of 11. does NOT place the application in condition for allowance because: In view of Applicants' amendment of claims 1, 2 and 37, deleting new matter, the previous rejection under 35 USC 112 (new matter) is hereby withdrawn. The examiner maintains the rejection of claims 1, 2, 6, 16-33, 37 and 38, under 35 U.S.C. §112, first paragraph (scope of enablement), as set forth on pp. 4-5 of the final office action dated July 9, 2008, for reasons of record. Applicants' claim amendments have addressed the grounds for rejection, only in part.

The previous office action indicated an enabled scope for the claimed method of proliferating cardiomyocytes in vitro, or in vivo comprising introducing into the nucleus of cardiomyocytes an adenoviral expression vector encoding cyclin D1, D2 or D3 and cyclin dependent kinase CDK4 or CDK 6, wherein said cyclin is operably linked to a nuclear localization signal, and wherein said adenoviral expression vector is introduced by direct injection into the myocardium. The action further indicated that any vector (as instantly claimed), that would include naked plasmid DNA would not impart sufficient gene expression. Further, such expression would be transient. Moreover, terminally differentiated, non-replicating cells, such as cardiomyocytes would be refractive to viral infection by retroviruses, that require actively dividing cells as hosts. Thus, any vector or any viral vector would not predictably provide sufficient directed delivery and expression of the cyclin and CDK genes, absent further undue experimentation.

Applicants traverse the rejection, arguing that the state of art establishes that the use of vectors is enabled, citing various U.S. Patents. Applicants' arguments have been fully considered, but are not found persuasive.

In response, it should be noted that while an enabled scope has been indicated for adenoviral expression vectors, instant base claims 1 and 2 are directed to any type of vector, that would include a bacterial plasmid, omitting an operably linked eukaryotic promoter necessary for the expression of the nuclear localization signal, the cyclin genes and a gene coding for CDK4 or CDK6. Further, each patent Application is examined on its own merits and the instant Application is separate and distinct from the Patents cited by Applicants. The instant claims encompass any vectors, including shuttle vectors, having no eukaryotic promoters. Moreover, the claimed cyclin and CDK genes and the nuclear localization signal are not operably linked to any eukaryotic promoter. Applicants have further not addressed the issue of retroviral vectors that would not infect non-dividing cardiomyocytes, and issues regarding naked bacterial plasmid vectors. Thus, the rejection is maintained for reasons of record and the foregoing commentary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.